

APR - 3 1996

Appendix 1**510(k) Summary*****Pulmo CT with Reference Database Option for SOMATOM CT Systems***

Submitted by:

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February 13, 1996

This 510(k) summary of safety and effectiveness information is being submitted in accordance with the requirements of SMDA 1990 and 21 CFR §807.92.

1. Contact Person:

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2. Device Name and Classification:

Trade Name:	Pulmo CT with Reference Database for the SOMATOM Plus and Plus 4 Computed Tomography Systems
Classification Name:	Computed Tomography X-ray System
CFR Section:	21 CFR §892.1750, Class II
Device Code:	90JAK

3. Substantial Equivalence:

The Pulmo CT with Reference Database option operating on SOMATOM Plus and Plus 4 CT scanners is substantially equivalent to the following devices:

- 1) Pulmo CT option in SOMATOM Plus CT
Siemens Medical Systems, Inc.
- 2) Pulmo CT option in SOMATOM Plus 4 CT
Siemens Medical Systems, Inc.

Both the Pulmo CT with Reference Database and Pulmo CT options are post-processing evaluation packages that involve respiratory gating, and as such do not affect the dosage characteristics or the imaging performance parameters of the SOMATOM CT scanners.

4. Device Description:

The Pulmo CT with Reference Database enables the user to obtain CT scans at defined respiratory levels through spirometric control. The patient is asked to breath through a spirometer and when the inspiration reaches a certain percentage (e.g., 50%) of the patient's vital capacity, the CT scan is triggered.

In addition to respiratory controlled triggering of CT scans, the Pulmo CT option provides the following evaluation capabilities:

- isolation of the left and right lungs
- automatic and interactive segmentation of the entire lung, or of central or peripheral regions,
- calculation and display of statistical parameters, including sub-range statistics (e.g., mean single-slice CT values),
- calculation and display of histograms of the entire lung, as well as the left and right, and
- calculation and display of volumes and partial volumes
- Comparison of the patient's averaged histograms and mean CT values with the adult reference database.

The adult reference database contains a collection of lung CT values (density) acquired using existing Pulmo CT option from patients with normal lung functions.

5. Intended Use of the Device:

The Pulmo CT with Reference Database is intended for diagnostic imaging. It provides highly reproducible CT values for pulmonary tissue, which is essential for follow up examinations and for providing quantitative support for diagnosis.

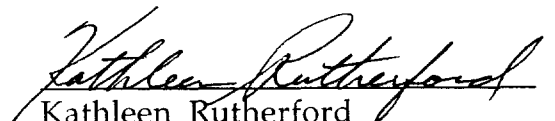
6. Summary of Technological Characteristics of the Device Compared to the Predicate Device:

The Pulmo CT with Reference Database has the same technological characteristics as the predicate Pulmo CT option, except the addition of a reference database and the histogram and mean values comparison function. They both control the spirometer, trigger the CT scans at the user defined trigger level, and provide evaluations and statistical analysis to the acquired images. The addition of the reference database and the comparison provides a reference for the clinical evaluation of pulmonary diseases.

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7. Clinical Study and Conclusion:

A multi-center clinical study was carried out in Europe to collect lung CT images from individuals with normal lung functions. The collected data, after statistical analysis, served as the reference database.


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